510(k) Summary: TRUSS™ Thoracolumbar Plate System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000
Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

Device Name: TRUSS™ Thoracolumbar Plate System

Classification: Per 21 CFR as follows:
§888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Codes KWQ.
Regulatory Class II. Panel code 87.

Predicate Device: GATEWAY® Thoracolumbar Plate System K062407
SE Date September 6, 2006
REVERE® Stabilization System K061202
SE Date July 20, 2006

Device Description:
The TRUSS™ Thoracolumbar Plate System consists of rigid and compression plates of various lengths that are used with variable or fixed angle bone screws. These plates attach to the anterolateral or lateral portion of the vertebral bodies of the thoracolumbar spine (T1-L5). Implants are composed of titanium alloy, as specified in ASTM F136, F1295 and F1472.

Intended Use:
The TRUSS™ Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

Basis of Substantial Equivalence:
The TRUSS™ Thoracolumbar Plate System implants are similar to the predicate Globus GATEWAY® Thoracolumbar Plate System K062407 and REVERE® Stabilization System K061202 with respect to technical characteristics, performance, and intended use. Mechanical testing in accordance with the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 is presented

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Globus Medical Inc.
% Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

AUG 13 2009

Re: K092108
Trade/Device Name: TRUSS™ Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: July 9, 2009
Received: July 14, 2009

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K092108

Device Name: TRUSS™ Thoracolumbar Plate System

Indications:

The TRUSS™ Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE ON THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MXM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092108